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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,213	02/08/2000	Mark G. Schrom	16724-108	2262

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/28/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/500,213

Applicant(s)

SCHROM ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 14-42 is/are pending in the application.
- 4a) Of the above claim(s) 16-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 14, 15 and 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 16-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8 and 10.

Applicant's election with traverse of the restriction in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the election is traversed. This is not found persuasive because the applicant did not point out why the election was incorrect.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, "deposited on said..." is vague since it sounds more like a method step than a structural recitation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 36, 37, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Willis (5433742). For claims 36 and 40, the recitation of "electroplated" is more like a method step than a structural limitation (the claimed limitation is directed to how the element is produced and is structurally equivalent to Willis's conductive links).

Claims 1-3, 11, 14, 15, 36, 37, and 39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Champeau (6208881). For the claims, the recitation of "electroplated" is more like a method step than a structural limitation (the claimed limitation is directed to how the element is produced and is structurally equivalent to Champeau's conductive links). In addition, for claim 14, splitting Champeau's electrode in half (or any amount) will provide a first and second segment. It is noted that the claim does not say the segments are separate segments.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 11, 36, 37, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotthardt et al (5016646) in view of Willis (5433742). For the claims, the recitation of "electroplated" is more like a method step than a structural limitation (the claimed limitation is directed to how the element is produced and is structurally equivalent to Gotthardt in view of Willis's conductive links).

Gotthardt discloses the claimed invention except for the electrodes being thin film electrodes. Willis teaches that it is known to thin film electrodes that are deposited on the body member and connected to the conductive links to provide a substantially smooth surface resulting in less irritation to the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes on the lead as taught by

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Gotthardt, with the use of thin film electrodes as taught by Willis, since such a modification would provide a lead with electrodes that are thin film electrodes that are deposited on the body member and connected to the conductive links to provide a substantially smooth surface resulting in less irritation to the body.

Claims 4-9, 14, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotthardt in view of Willis (or as being unpatentable over Champeau alone).

Gotthardt in view of Willis (or Champeau) discloses the claimed invention except for the outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), the conductors having an angle between each turn of 10 to about 80 degrees (claims 7 and 38) and the electrodes being in overlapped relation (claim 14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Gotthardt in view of Willis (or Champeau), with an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), the conductors having an angle between each turn of 10 to about 80 degrees (claims 7 and 38) and the electrodes being two segments in overlapped relation (claim 14) since it was known in the art that leads have: an outer diameter of the lead being about 2 French and internal diameter being 0.012 inch to allow the lead to unobtrusively be placed in small areas of the body and to prevent tissue damage and irritation (claim 4); the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5) to provide a small diameter lead with flexibility in particular directions; the conductors having an angle between each turn of 10 to

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about 80 degrees to provide greater or lesser stiffness and flexibility; and the electrodes being segments in overlapped relation to provide different pulses to or bipolar pulses to a specific area in the body.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Gotthardt in view of Willis (or Champeau) with the outer diameter being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), and the conductors having an angle between each turn of 10 to about 80 degrees, because Applicant has not disclosed that the outer diameter being about 2 French and internal diameter being 0.012 inch (claim 4), the conductors having a substantially rectangular cross section, 0.004 inch wide by 0.992 inch high (claim 5), and the conductors having an angle between each turn of 10 to about 80 provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thin electrode lead having circular conductors in a helical pitch as taught by Gotthardt in view of Willis (or Champeau) because it will provide a small body implantable flexible lead that is easily and quickly produced.

Therefore, it would have been an obvious matter of design choice to modify Gotthardt in view of Willis(or Champeau) to obtain the invention as specified in the claim(s).

### ***Response to Arguments***

Applicant's arguments filed 4/10/03 have been fully considered but they are not persuasive. The argument that Willis, Gotthardt, or Champeau do not show electroplated conductive links is not persuasive since that limitation is directed to the way the conductive links

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are made (a product by process) and not to a structural limitation of the conductive links. The patentability of a product does not depend on its method of production. Please see MPEP 2113.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko  
Primary Examiner  
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GRE  
May 26, 2003